

4.0 REFERENCE DATA

The ability of a test substance to bind to the ER *in vitro*, whether to an isolated protein receptor molecule or to ERs in cultured cells, suggests, but does not demonstrate, the ability of the substance to act as an estrogen agonist or antagonist. A commonly used *in vitro* method to measure such biological effects is based on an assessment of the ability of a substance to induce or inhibit transcriptional activation of an ER-dependent reporter gene function.

The purpose of this BRD is to assess the sensitivity of various *in vitro* ER binding assays for detecting ER-binding substances with various binding activities and to assess reliability within and among laboratories and across procedures. No attempt is made to evaluate their performance with respect to other *in vitro* biological end points, such as transcriptional activation, or *in vivo*, such as promotion of uterine growth. Such comparisons will be addressed elsewhere. Therefore, no reference data are included for assessing the biological relevance of the ER binding assays.

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